Orchestra BioMed and Terumo Enter into New $30 Million Virtue SAB Strategic Agreements

October 28, 2025

- *New agreement grants Terumo Virtue SAB coronary indication right of first refusal and supersedes prior distribution agreement*
- *Terumo to pay a total of $30 million to Orchestra BioMed*
- *Orchestra BioMed retains all development and distribution rights to Virtue SAB in all indications*
- *Orchestra BioMed recently initiated patient enrollment for the Virtue Trial, its U.S. pivotal IDE trial of Virtue SAB in the treatment of coronary in-stent restenosis ("ISR")*

NEW HOPE, Pa., Oct. 28, 2025 (GLOBE NEWSWIRE) -- Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO, "Orchestra BioMed" or the "Company"), a biomedical company accelerating high-impact technologies to patients through strategic partnerships with market-leading global medical device companies, today announced that it has entered into a termination and right of first refusal agreement (the "ROFR Agreement") with Terumo Corporation (TYO:4543) and Terumo Medical Corporation (collectively, "Terumo") with respect to Virtue® Sirolimus AngioInfusion™ Balloon ("SAB") for the treatment of coronary artery disease worldwide. The ROFR Agreement, which supersedes and terminates the prior Virtue SAB distribution agreement between Orchestra BioMed and Terumo (the "Prior Agreement"), grants Terumo a right of first refusal ("ROFR") to acquire the rights, or enter a distribution arrangement, with respect to Virtue SAB for the treatment of coronary artery disease, in exchange for an upfront payment of $10 million. Terumo and Orchestra BioMed have also entered into a securities purchase agreement, pursuant to which Terumo has agreed to invest an additional $20 million in Orchestra BioMed through a new series of non-voting preferred stock, which is convertible into common stock in the future, subject to certain conditions, at a minimum of $12 per share (the "Securities Purchase Agreement"). Terumo previously made a $30 million non-refundable payment and $5 million common stock investment in Orchestra BioMed upon execution of the Prior Agreement.

David Hochman, Chairman and Chief Executive Officer of Orchestra Biomed stated: "Our new agreements with Terumo reflect the differentiated value of Virtue SAB for the treatment of atherosclerotic disease in the coronary arteries and provide strategic optionality for both companies. This new arrangement highlights the strong clinical and commercial potential of Virtue SAB to become a best-in-class therapy in the global coronary market. The $30 million in proceeds from Terumo provides meaningful additional capital resources to advance both of our pivotal stage programs to key clinical and regulatory milestones. We are glad to be aligned with our colleagues at Terumo and are thrilled to have initiated the Virtue Trial evaluating our fundamentally different approach to treating coronary in-stent restenosis."

Ghada Farah, President of Terumo Interventional Systems commented: "We are very pleased to enter into a new strategic agreement with Orchestra BioMed that reflects the significant potential for Virtue SAB in the treatment of coronary artery disease. We believe it aligns the objectives of both companies, and we wish Orchestra BioMed great success as they enroll patients in the Virtue Trial."

The ROFR Agreement
Under the ROFR Agreement, Orchestra BioMed will have the opportunity to seek development and commercialization partnerships for Virtue SAB in any therapeutic indication, including coronary artery disease treatment. Terumo will have the first right to review and respond to any potential third party offers presented to Orchestra BioMed related to the global coronary market. The ROFR period expires ninety (90) days after Orchestra BioMed discloses primary endpoint data from the Virtue Trial to Terumo or the public, whichever is earlier (the "ROFR period").

The transactions contemplated by the ROFR Agreement and the Securities Purchase Agreement are subject to customary closing conditions and are expected to close no later than November 7, 2025.

About Orchestra BioMed
Orchestra BioMed is a biomedical innovation company accelerating high-impact technologies to patients through strategic collaborations with market- leading global medical device companies. The Company's two flagship product candidates - Atrioventricular Interval Modulation (AVIM) Therapy and Virtue® Sirolimus AngioInfusion™ Balloon (Virtue SAB) - are currently undergoing pivotal clinical trials for their lead indications which both represent multi-billion-dollar annual global market opportunities. AVIM Therapy is a bioelectronic treatment for hypertension, the leading risk factor for death worldwide, and is designed to be delivered as a firmware upgrade to a pacemaker and achieve immediate, substantial and sustained reductions in blood pressure in patients with hypertensive heart disease. The Company has a strategic collaboration with Medtronic for the development and commercialization of AVIM Therapy for the treatment of uncontrolled hypertension in pacemaker-indicated

patients. AVIM Therapy has FDA Breakthrough Device Designation for these patients as well as an estimated 7.7 million total patients in the U.S. with uncontrolled hypertension despite medical therapy and increased cardiovascular risk. Virtue SAB is a highly differentiated, first-of-its-kind drug delivery angioplasty balloon system designed to deliver a proprietary extended-release formulation of sirolimus, SirolimusEFR™, for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide. Virtue SAB has been granted Breakthrough Device Designation by the FDA for the treatment of coronary ISR, coronary small vessel disease and below-the-knee peripheral artery disease. The Company has a right of first refusal agreement with Terumo Corporation and Terumo Medical Corporation, a leading global medical device company, for a potential transaction related to Virtue SAB for the treatment of coronary artery disease. For further information about Orchestra BioMed, please visit www.orchestrabiomed.com, and follow us on LinkedIn.

About Virtue SAB
Virtue SAB is a highly differentiated, first-of-its-kind drug delivery angioplasty balloon system designed to deliver a proprietary extended-release formulation of sirolimus, SirolimusEFR™. It uses a non-coated microporous AngioInfusion™ Balloon to protec the drug in transit and consistently deliver a large liquid dose, overcoming certain limitations of drug-coated balloons. SirolimusEFR delivered by Virtue SAB has been shown in published preclinical series involving hundreds of arterial deliveries to achieve sustained tissue levels well above the known required therapeutic tissue concentration for inhibiting restenosis (1 ng/mg tissue) for the entire critical healing period of approximately 30 days. Virtue SAB demonstrated positive three-year clinical data in coronary ISR in the SABRE study, a multi-center prospective, independent core lab-adjudicated clinical study of 50 patients conducted in Europe. Virtue SAB has been granted Breakthrough Device Designation by the FDA for the treatment of coronary ISR, coronary small vessel disease and peripheral artery disease below-the-knee.

About Coronary In-Stent Restenosis (ISR)
Coronary ISR is a serious complication of coronary stenting, which can increase the risk of life-threatening heart problems. It is characterized by a re-narrowing of a coronary artery segment that was previously treated with a stent. According to the National Cardiovascular Data Registry, coronary ISR occurs in up to 10% of stented patients during the first year and continues at a rate of up to 3% per year thereafter, resulting in an estimated over 325,000 coronary ISR lesions annually worldwide that may require treatment. The only device treatments currently approved by the FDA for use in coronary ISR lesions are balloon angioplasty and intravascular radiation therapy known as brachytherapy. Traditional balloon angioplasty has high retreatment rates and brachytherapy is considered a last resort treatment due to radiation burden, expense, limited availability, and long-term requirement for dual antiplatelet therapy. If left untreated, coronary ISR may lead to stable angina, unstable angina, acute coronary syndrome, acute myocardial infarction, or death.

References to Websites and Social Media Platforms

References to information included on, or accessible through, websites and social media platforms do not constitute incorporation by reference of the information contained at or available through such websites or social media platforms, and you should not consider such information to be part of this press release.

Forward-Looking Statements
Certain statements included in this press release that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "would," "plan," "predict," "potential," "seem," "seek," "future," "outlook" and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements relating to the closing of the transactions contemplated by the ROFR Agreement and the Securities Purchase Agreement, the timing of the initiation of the Virtue Trial, and the potential safety and efficacy of the Company's product candidates. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of the Company's management and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as and must not be relied on as a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and may differ from assumptions. Many actual events and circumstances are beyond the control of the Company. These forward-looking statements are subject to a number of risks and uncertainties, including changes in domestic and foreign business, market, financial, political, and legal conditions; risks related to regulatory approval of the Company's product candidates; the timing of, and the Company's ability to achieve, expected regulatory and business milestones; the impact of competitive products and product candidates; and the risk factors discussed under the heading "Item 1A. Risk Factors" in the Company's annual report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 31, 2025, as updated by any risk factors disclosed under the heading "Item 1A. Risk Factors" in the Company's subsequently filed quarterly reports on Form 10-Q.

The Company operates in a very competitive and rapidly changing environment. New risks emerge from time to time. Given these risks and uncertainties, the Company cautions against placing undue reliance on these forward-looking statements, which only speak as of the date of this press release. The Company does not plan and undertakes no obligation to update any of the forward-looking statements made herein, except as required by law.

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